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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,084	06/26/2003	Larry Chen	APGR-00301-UUS	4274

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EXAMINER

JOHNSEN, JASON H

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,084

Applicant(s)

CHEN, LARRY

Examiner

Jason H. Johnsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 6/26/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-10 is/are allowed.
- 6) ☐ Claim(s) 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on N/A is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>N/A</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112 - First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 11 is directed to a method of treating cancer. The term cancer is interpreted to include any and all forms of cancer that are characterized by angiogenesis as well as the specific locations of cancers as in the stomach, liver, lung, cervix and breasts. Furthermore, claims 12-16 narrow the focus of what kinds of cancers can be treated with applicant's compounds and compositions, but is still seen as un-enabling for all of the broad categories of cancers listed in these claims. In light of this, it can be asserted that in spite of the vast expenditure of human and capital resources in recent years, no one drug has been found which is effective in treating all types of cancer because it is not a simple disease, nor is it even a single disease, but a complex of a multitude of different entities, each behaving in a different way. In re Hozumi, 226 USPQ 353 (ComrPats 1985).

Moreover, the determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion

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reached by weighing all the factual considerations. In re Wands, 8 USPQ2d 1400 (CAFC).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include but are not limited to:

1. The breadth of the claims;
2. The nature of the invention;
3. The state of the prior art;
4. The level of one of ordinary skill;
5. The level of predictability in the art;
6. The amount of direction provided by the inventor;
7. The existence of working examples; and
8. The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Wands Analysis

1. The Breadth of the Claims.

The breadth of the instant claims are seen to encompass compounds or pharmaceutical compositions for the treatment of all forms of cancers as well as methods for the treatment of cancer that are characterized by way of reproducing singlet state oxygen radicals and superior cell cytotoxicity. The claims are drawn to treating specific locations of cancers found in the stomach, liver, lung, cervix and breasts. Moreover, the term "treatment" is interpreted as encompassing the alleviation of symptoms associated with the disease or disorder, or stopping the further progression or worsening of those symptoms of the disease or disorder.

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2. The Nature of the Invention.

The nature of the invention is the treatment of cancer broadly, as well as the treatment of various carcinomas, leukemia's and lymphomas. Currently, there are no known agents that treat cancers all inclusively.

3. The State of the Prior Art.

The applicant has referenced several articles in the disclosure in order to demonstrate the state of the prior art on June 26th, 2003. A close reading of the prior art does not reveal that the art claimed recognizes compounds similar or analogous to those with the ability to treat or prevent cancer. In addition the applicant has submitted three experimental examples to determine the anticancer activity of present compounds. These examples show only the use of a breast cancer cell line, apoptosis of a MCF-7 cell line, and B cell lymphoma cancer cell line. Though the applicant has demonstrated through examples that there may possible anticancer activity in breast cancer cell lines, mouse B cell lymphoma cell lines and apoptosis of a MCF-7 cell line, this does not demonstrate anticancer activity broadly in all forms of cancer or in other locations of the human or mammalian anatomy. Therefore, the example only shows that the state of the art to the extent of the form of cancer mentioned.

4. The Level of Ordinary Skill

In this case, it is important to determine the level of skill in the art at the time at which the applicant claims priority, that being June 26, 2003. The level of skill is that of one with a doctoral understanding of cancer therapeutics.

5. The Level of Predictability in the Art

The treatment of cancer is highly unpredictable due to the differing forms of cancerous cells, their location, their potential for metastases, the fact that cancer therapeutics is palliative rather than curative and that cancer treatment readily harms normal tissues (see Katzung pp. 881-882).

6. The Amount of Direction Provided by the Inventor

The applicant has not demonstrated sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or reference to the same in the prior art to provide a skilled artisan with sufficient guidance to practice the instant treatment of cancer claimed. For example, the applicant only discloses that dosages should be in a therapeutically effective amount.

7. The Existence of Working Examples

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 27 USPQ2d 1510 (CAFC). The disclosure does not demonstrate sufficient evidence to support the applicant's claim to the treatment of cancer broadly, or the less narrow, but still broad categories of carcinomas, lymphomas and leukemia. There are not sufficient representations in the disclosure or data from references of the prior art to provide a nexus between those examples and a method of treating cancer with the claimed compound other than the claimed compound having anticancer activity in breast cancer cell lines and B Cell lymphoma cell lines.

8. The Quantity of Experimentation Needed to Make or Use the Invention Based on the Content of the Disclosure

In order for there to be a method of treating cancer generally, as claimed by the applicant, it would be necessary to show that a vast range of different types of cancers can be treated that have differing cell types, locations and potentials for metastases. Furthermore, direction, in the form of examples, must be shown to determine what a therapeutically effective dose may be. The references submitted do not demonstrate this. Therefore, one of ordinary skill in the art would require a significant amount of experimentation in order to determine the effective dosage to treat or prevent the multitudes of different types of cancer with the claimed compounds, pharmaceutical compositions in combination with other therapeutic agents (See Katzung pp. 882-884).

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 and 16 recite the limitation “method of claim 14, wherein the leukemia is one of...” and “method of claim 14, wherein the lymphoma is one of...” respectively. There is insufficient antecedent basis for these limitations in the claims because claim 14 does not teach the limitation of leukemia or lymphoma from which claim 15 and 16 depend from and further limit the scope of.

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Conclusion

The technical features of the compounds and compositions found in claims 1-10 are seen to be free from the prior art and these limitations are not taught or fairly suggested by the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason H. Johnsen** whose telephone number is **571-272-3106**.

The examiner can normally be reached on Mon-Friday, 8:30-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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